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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Marc Feldmann and Ravinder N. Maini
Serial No. : 09/754,004 Examiner: P. Gambel
Filed : January 3, 2001 Group Art Unit: 1644
For : TNF α ANTAGONISTS AND METHOTREXATE IN THE
TREATMENT OF TNF-MEDIATED DISEASE

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June 20, 2003

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INFORMATION DISCLOSURE STATEMENT

In accordance with their duty of disclosure under 37 C.F.R. §1.56, applicants would like to direct the Examiner's attention to the following publications which are listed on the attached Form PTO-1449 (**Exhibit A**). Copies of cited publications 5, 7-11, 20-22, 24-27, 29, 32, 34, 36, 39-41, 43-47, 49, 52 and 53 are attached hereto as **Exhibits 1 - 28**, respectively. Publications 1, 2, 12-19, 30, 31, 33, 48 and 51 were entered in prior application U.S. Application No. 08/958,248, filed October 6, 1993, to which priority under 35 U.S.C. §120 is claimed. Publications 4, 6, 38, 42 and 50 were entered in prior application U.S. Application No. 08/607,419, filed February 28, 1996, to which priority under 35 U.S.C. §120 is claimed. Publications 3, 23, 28, 35 and 37 were entered in prior application U.S. Application No. 08/690,775, filed August 1, 1996, now U.S. Patent No. 6,270,766 B1, issued August 7, 2001, to which priority under 35 U.S.C. §120 is claimed. According to 37 C.F.R.

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§1.98(d), copies of patents or publications that were previously cited by, or submitted to, the Office in connection with such prior applications need not accompany the Information Disclosure Statement.

1. U.S. Patent No. 5,096,906, issued March 17, 1992, Mandell, et al.;
2. U.S. Patent No. 4,695,459, issued September 22, 1987, Steinman, et al.;
3. U.S. Patent No. 5,656,272, issued August 6, 1997, Le, et al.;
4. U.S. Patent No. 5,502,066, issued March 26, 1996, Heinemann, et al.;
5. U.S. Patent No. 5,658,570, issued August 19, 1997, Newman, et al. (**Exhibit 1**);
6. U.S. Patent No. 5,580,873, issued December 3, 1996, Bianco, et al.;
7. U.S. Patent No. 5,298,396, issued March 29, 1994, Kotzin, et al. (**Exhibit 2**);
8. U.S. Patent No. 5,468,481, issued November 21, 1995, Sharma, et al. (**Exhibit 3**);

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9. U.S. Patent No. 5,260,422, issued November 9, 1993, Clark, et al. (**Exhibit 4**);
10. U.S. Patent No. 5,204,329, issued April 20, 1993, Ackerman, et al. (**Exhibit 5**);
11. U.S. Patent No. 5,994,510, issued November 30, 1999, Adair, et al. (**Exhibit 6**);
12. PCT International Application Publication No. WO 92/07076, published April 30, 1992;
13. PCT International Application Publication No. WO 91/10722, published July 25, 1991;
14. PCT International Application Publication No. WO 90/15152, published December 13, 1990;
15. European Patent Application No. EP 0 240 344, published October 7, 1987;
16. Australian Patent Application No. AS 58976/90, published September 22, 1987;
17. Canadian Patent No. 2,021,369, issued January 19, 1991;
18. German Patent No. DE 40 06 269 A1, issued February 28, 1990;

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19. British Patent Application No. GB 2 246 569 A, published June 15, 1990;
20. Arend, W.P., et al. (1990) Arthritis Rheum. 33(3):305-315
(Exhibit 7);
21. Bach, J.F. (1993) TiPs 14:213-216 (Exhibit 8);
22. Barrera, P., et al. (1995) Br. J. Rheumatol. 34:747-755
(Exhibit 9);
23. Bologna, C., et al. (1996) Presse Med. 25:876-878,
XP002048553;
24. Brennan, et al. (1994) Clin. Exp. Immunol. 97:1-3 (Exhibit
10);
25. Cooper, K.D. (1993) Clin. Rev. Allergy 11:543-559 (Exhibit
11);
26. Elliott, M.J., et al. (1994) Int. Arch. Allergy Immunol.
104:112-125 (Exhibit 12);
27. Feldmann, M., et al. (1996) Ann. Rev. Immunol. 14:397-440
(Exhibit 13);
28. Flesch (1992) Blood 79:3366-3368;
29. Fries, J.F., et al. (1990) J. Rheumatol. 17(22):12-15 (Exhibit
14);

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30. Genzyme Catalog (1991) pp. 79-80;
31. Harris, et al. (1993) Tibtech 11:42-44;
32. Herzog, C., et al. (1987) Lancet 2(8573):1461-1462 (**Exhibit 15**);
33. Hozzof, et al. (1987) Lancet 11:1461-1462;
34. Kahan, B.D. (1992) Curr. Opin. Immunol. 4:553-560 (**Exhibit 16**);
35. Kalden, J.R., et al. (1995) Curr. Opin. Rheum. 7: (3)191-197;
36. Littman, B.H., et al. (1995) Arthritis Rheum. 38:29-37 (**Exhibit 17**);
37. Maini, R.N. (1996) J. Royal College of Physicians of London 30(4):344-351;
38. Maini, R.N. (1995) Arth. Rheum. Suppl. 38(9):S186 (Abstract 200);
39. Matsumiya, G., et al. (1996) Transplant Proceed. 28(2):751-753 (**Exhibit 18**);
40. Moreland, L.W., et al. (1995) Arthritis Rheum. 38:1581-1588 (**Exhibit 19**);

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41. Moreland, L.W., et al. (1996) J. Rheumatol. (Supplemental 44) 23:78-83 (**Exhibit 20**);
42. Piguet, et al. (1992) Immunology 77:510-514;
43. Qin, S., et al. (1987) Eur. J. Immunol. 17:1159-1165 (**Exhibit 21**);
44. Richardson, C., et al. (1995) Br. J. Clin. Prac. 49:135-139 (**Exhibit 22**);
45. Sander, O., et al. (1995) Arthritis Rheum. 38:S266 (Abstract 678) (**Exhibit 23**);
46. Sosman, J.A., et al. (1993) J. Pediatric Hematol. Oncol. 15(2):185-195 (**Exhibit 24**);
47. Stein, C.M., et al. (1994) Arthritis Rheum. 37:S252 (**Exhibit 25**);
48. Strober, et al. (1990) Immunol. Reviews 118:233-255;
49. Stuart, et al. (1986) Laboratory Investigation 34:1-13 (**Exhibit 26**);
50. Thorbecke, et al. (1992) Proc. Natl. Acad. Sci. USA 85:7375-7379;
51. Waldmann, T.A. (1991) Science 252:1657-1662;

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52. Weinblatt, M.E., et al. (1994) Arthritis Rheum. 37:1492-1498
(**Exhibit 27**); and

53. Decision on Appeal, issued March 21, 2003, for U.S. Serial No.
09/093,458, filed June 8, 1998 (**Exhibit 28**).

Applicants request that the Examiner review the publications and
make them of record in the subject application.

This Information Disclosure Statement is being submitted after the
mailing of a first Office Action. Under 37 C.F.R. §1.97(c), an
Information Disclosure Statement shall be considered by the Office
if filed by the applicant after the period specified in paragraph
(b) of this section (i.e., the mailing of a first action on the
merits), provided that the Information Disclosure Statement is
filed before the mailing date of... a final action under §1.113...,
and is accompanied by: (1) the statement specified in paragraph (e)
of this section; or (2) the fee set forth in §1.17(p).

Pursuant to 37 C.F.R. §1.17(p), the fee for filing an Information
Disclosure Statement is ONE HUNDRED EIGHTY DOLLARS (\$180.00) and a
check including this amount is enclosed. Accordingly, applicants
request that this Information Disclosure Statement be considered.

If a telephone interview would be of assistance in advancing
prosecution of the subject application, applicants' undersigned
attorneys invite the Examiner to telephone them at the number
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No fee, other than the \$180.00 fee for filing an Information Disclosure Statement, is deemed necessary in connection with the filing of this Information Disclosure Statement. However, if any additional fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,



I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Alan J. Morrison
Reg. No. 37,399

Date

John P. White
Registration No. 28,678
Alan J. Morrison
Registration No. 37,399
Attorneys for Applicants
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, New York 10036
Tel. No. (212) 278-0400